

REMARKS

In the Office Action dated May 2, 2007, claims 1, 2, 4, 6-8, 10-19, 22-32, 54-84 and 86-89 are rejected. Claims 1-2, 6, 19, 25-26, 54, 61, 64-65, 68-70, and 80 are amended herein. Claims 18, 22-24, 32, 56, 63, 66-67, 72 and 78 have been cancelled herein. Amendments have been made without prejudice or disclaimer. No new matter has been added. For the reasons set forth below, applicants submit that the pending claims are in condition for immediate allowance. Reconsideration is respectfully requested.

Specification

The applicants respectfully submit that the claim limitations in the Present Application, as amended, do not contain the required "means for" or "step for" language as required to invoke 35 U.S.C. 112, sixth paragraph. More specifically, claim 32 has been cancelled herein. As such, without a showing that even though the phrase "means for" or "step for" is not used, that a claim limitation has been written as a function to be performed without reciting sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112, sixth paragraph, the Present Application does not invoke 35 U.S.C. 112, sixth paragraph. (M.P.E.P. 2181).

Accordingly, applicants respectfully request the removal of the objection to the disclosure.

Claim Objections—Claim 32

Claim 32 has been cancelled herein, mooted a response to the objection thereof.

Claim rejections—35 U.S.C. § 102(e)

Claims 1-2, 4, 6-8, 10-19, 22-32, 54-71, 73-74, 76-84 and 87-89 are rejected as allegedly being anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,607,508 to Knauer. Claims 18, 22-24, 32, 56, 63, 66-67, and 78 have been cancelled herein,

mooting the rejection thereof. Applicants respectfully traverse the remaining rejection because Knauer does not disclose each and every element of independent claims 1, 19, 54, 61 and 80 or those claims directly or indirectly dependent therefrom.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Likewise, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Amended independent claim 1 recites a medical device comprising a vial holder displaceable within the barrel having a socket configured to receive the vial and *an air-pump chamber within the barrel configured to pump air into the vial*. Claim 1 also recites a transfer seal disposed within the barrel between the transfer chamber and the air-pump chamber.

Amended independent claim 19 recites a holder configured to receive a vial and an air-pump chamber configured to pump air into the vial. Claim 19 also recites a transfer seal disposed between the air-pump chamber and a transfer chamber.

Similarly, amended independent claim 54 recites a pre-filled container of medicinal fluid and a pressurizing element within a housing to provide *positive fluid pressure* within the container. Claim 54 also recites a transfer seal between a chamber and the pressurizing element.

Independent claim 61, as amended herein, recites an air-pump chamber disposed within a holder and a piston operable to pump air from the air-pump chamber into the vial to provide positive air pressure within the vial.

Amended independent claim 80 recites a socket for receiving a vial of medicinal fluid, wherein the socket includes a piston to provide positive fluid pressure within the vial.

The Office Action, on page 4, alleges that Knauer discloses a medical device (600) comprising a hollow barrel (400), a vial holder (near 300), and a pressuring element (near 303). However, Knauer does not disclose an air-pump chamber element

or a piston configured to pump air into the vial. More specifically, referring to FIG. 5 (see below), Knauer discloses:

"As the plunger rod translates away from the front end of the injector body [400], a volume is created between the plunger [303] and the syringe barrel [302]. The seal between the plunger and the syringe ensures that the volume is created under a vacuum. The medicament in the vial, *under ambient pressure*, is pushed into the volume between the plunger and the syringe barrel." (Knauer, column 4, lines 54-61, emphasis added).

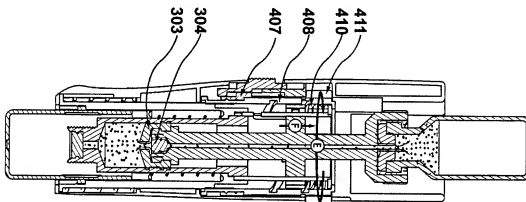


FIG. 5 of Knauer

As shown by FIG. 5 above, as the plunger 303 of Knauer is withdrawn, it creates a volume below the plunger 303 that is under a vacuum that is much lower in pressure than that of the ambient pressure in the vial. The plunger 303 of Knauer does not pump air into the vial. As such, the fluid in the vial is under ambient pressure and is pushed out into the low pressure of the vacuum. Accordingly, applicants respectfully submit that Knauer does not disclose an air-pump chamber, piston, or a pressurizing element configured to pump air into a container or vial and create a positive pressure therein as recited by independent claims 1, 19, 54, 61 and 80.

Furthermore, Knauer does not disclose a transfer seal disposed between a transfer chamber and air-pump chamber as recited by independent claims 1 and 19. Moreover, Knauer does not disclose a transfer seal between a pressurizing element and the chamber for receiving the medicinal fluid as recited by amended independent claim 54. Likewise, Knauer fails to disclose a lock configured to releasably lock the holder and the barrel to prevent relative motion between the holder and the barrel as recited by amended independent claim 61. In further regard to amended independent claim 61, Knauer does not disclose a socket formed in a holder, wherein the holder is displaceable relative to a piston. Also, Knauer does not disclose a transfer seal positioned between a socket and chamber as recited by amended independent claim 80.

Therefore, Knauer does not disclose each and every element of independent claims 1, 19, 54, 61 and 80, and those claims dependent therefrom. For the foregoing reasons, applicants respectfully request removal of the rejection of claims 1-2, 4, 6-8, 10-19, 25-31, 54-55, 57-62, 64-71, 73-74, 76-77, 79-84, and 87-89 under 35 U.S.C. § 102(e).

Claim rejections—35 U.S.C. § 103

Claims 12, 59, 75 and 86

Claims 12, 59, 75 and 86 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Knauer in view of U.S. Patent No. 4,972,843 to Broden. Claim 12 depends from independent claim 1, claim 59 depends from independent claim 54, claim 75 depends from independent claim 61, and claim 86 depends from independent claim 80.

To establish and maintain a *prima facie* case of obviousness under 35 U.S.C. § 103, M.P.E.P. § 706.02(j) states that the prior art reference must teach or suggest all the claim elements.

For the same reasons discussed in the previous section, Knauer in combination with Broden do not obviate claims 12, 59, 75 and 86, which depend from patentable independent claims. As such, applicants respectfully request that the rejection of claims 12, 59, 75 and 86 under 35 U.S.C. § 103 (a) be withdrawn.

Claim 72

Claim 72 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Knauer in view of U.S. Patent No. 4,861,335 to Reynolds. Applicants note that claim 72 is cancelled herein, mooted a response to the rejection thereof.

CONCLUSION

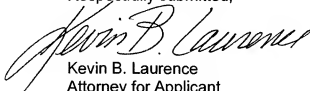
In view of the foregoing, Applicants submit that the claims define patentable subject matter and a Notice of Allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact Applicants' attorney at the telephone number given herein.

Please continue sending all correspondence to Paul Evans at the following address: (Customer No. 26,152).

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DATED this 29TH day of August, 2007.

Respectfully submitted,



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